K023098

Section D

Premarket Notification – 510(k)
Summary of Safety and Effectiveness
for Accufuser, Accufuser Plus and Standard Procedure Kit

DEC 0 9 2002

Premarket Notification – 510(k)
Summary of Safety and Effectiveness
for Accufuser, Accufuser Plus and Standard Procedure Kit

Date Prepared: September 17, 2002

Trade Name: Accufuser; Accufuser Plus; Standard Procedure Kit

Common Name: Elastomeric Infusion Pump Kit

Classification Name: Pump, Infusion, Elastomeric

Classification Panel: General Hospital and Personal Use Device

Device Classification Regulation Number: 880.5725, Class II

Panel: 80

Procode: MEB

Existing Device Cleared 510(k): K003915, Accufuser and Accufuser Plus

Predicate devices demonstrating substantial equivalence include the following.

- K013928, Breg Corporation, Pain Care 3000 and 3200, and accessory Kit.
- K014091, Stryker Pain Pump and Accessory Kit.
- K020862, I-Flow, Infusion Pump and Administration Set.

Submitted by:

McKinley Infuser, LLC
631 Howard, #202
San Francisco, CA 94105 USA
Phone: 415-543-2196
Contact for questions: John Chappell, RAC
Establishment Registration Number: 3003468679
Owner/Operator Number: 9047569

This submission is intended to notify the Food and Drug Administration that McKinley Infuser, LLC intends to market a modification to an existing device (K003915) called the Accufuser/Accufuser Plus and Standard Procedure Kit. Modifications to the existing device include two new indications for use, expansion of the bolus delivery range, addition of two bolus lockout times, addition of one reservoir volume size through combining two reservoirs, addition of flow rates for bolus devices and addition of a standard procedure kit.

The Accufuser/Accufuser Plus system and its predicate device (K020862) are intended for use as follows.

The Accufuser and Accufuser Plus systems are intended for general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, intra-arterial and epidural, and into the intra-operative (soft tissue / body cavity) site. The Accufuser Plus is also intended for patient-controlled infusion using the integrated bolus button. General infusion uses include pain management for preoperative, perioperative and postoperative surgery.

The Accufuser and Accufuser Plus systems are also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

The Accufuser/Accufuser Plus system is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

Description of the Accufuser System

The Accufuser/Accufuser Plus system consists of a pump and an integrated administration set. The pump is a continuous silicone balloon type. The pump provides continuous fluid delivery with an attached, fixed rate administration set. The pumps are supplied as fixed flow rates. A silicone balloon is used as both the fluid reservoir of the device and the pressure (energy) source.

The Accufuser/Accufuser Plus pump and administration set are intended for single patient use.

The Accufuser Plus is the Accufuser with the addition of a Patient Medication Control Module (PCM). The PCM allows the patient to administer a bolus of a fixed volume with a fixed lockout (re-fill) time. The PCM in integrated into the administration set with a bolus button that allows the patient controlled administration of medication as needed.

The Standard Procedure Kit is substantially equivalent to the predicate devices. The kit includes various kit components such as catheter, needle, syringe, y adapter, dressing, tape, gauze and carry case.

Device Specifications and Safety Functions

The Accufuser/Accufuser Plus system has fill volumes and flow rates substantially equivalent to the pumps of the named predicate devices.

The Accufuser/Accufuser pumps and the identified predicate device use either a glass orifice or PVC tubing to control the flow rate.

The Accufuser/Accufuser Plus provides a fixed flow and is not subject to fluid runaway conditions similar to that of some electronic pumps.

All fluid path materials of the Accufuser/Accufuser Plus system are in conformance with ISO 10993 Part 1.

There are currently no approved performance standards established for elastomeric infusion pumps under Section 514 of the Food, Drug and Cosmetic Act.

Packaging is suitable for ETO sterilization.

ETO is the validated sterilization method.

Product Configuration:

- Reservoir volume range is from 60 ml to 550 ml.
- Flow rate range is 0.5 ml/hr to 10.0 ml/hr.
- Bolus levels are 0.5 ml, 1.0 ml and 2.0 ml.
- Lockout times range from 6 minutes to 60 minutes and include increments of 6, 8, 15, 30 and 60 minutes.

Materials:	PET-G, ABS, polypropylene, silicone, PVC, polycarbonate, cellulose acetate, PTFE, and acrylic. DEHP-Free. Plasticizer used is TOTM, Tri-Octyl Trimellitate. Latex-Free.
Filter:	1.2 Micron, air-eliminating, in-line filter

System Accuracy

Reservoir Volume	Accuracy
60 ml	+/- 10% of nominal flow rate at 95% confidence interval
100 ml	+/- 10% of nominal flow rate at 95% confidence interval
275 ml	+/- 15% of nominal flow rate at 95% confidence interval
550 ml	+/- 15% of nominal flow rate at 95% confidence interval

Operating Pressure	5 to 6 psi
System Residual Volume	< 3 ml (includes tubing and reservoir)
Operating Temperature:	The Accufuser and Accufuser Plus systems are calibrated to deliver solution at the labeled nominal

flow rate when the temperature of the infusate in the flow restrictor (distal end) is 32° C / 89.6°F (normal skin temperature). Flow rate increases approximately 1% per 1°F / 0.56°C increase in temperature.

Fluid Viscosity: The Accufuser and Accufuser Plus systems are calibrated using 5% Dextrose in Water (D5W) as the infusate. Flow rate increases as fluid viscosity decreases. (E.g., Using sterile water as diluent will increase the flow rate by approximately 10%.)

Head Height: The Accufuser and Accufuser Plus systems are calibrated with zero head height. Increased head height will cause increased flow rate. (E.g., +43 cm / +17" of head height will increase flow rate by approximately 12%.)

Conclusion:

The Accufuser/Accufuser Plus and Standard Procedure Kit does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. The Accufuser/Accufuser Plus system and accessory Standard Procedure Kit is substantially equivalent to the named predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 9 2002

Mr. John Chappell
Regulatory Affairs
McKinley Infuser, LLC
631 Howard Street, Suite 202
San Francisco, California 94105

Re: K023098
Trade/Device Name: Accufuser, Accufuser Plus, Standard Procedure Kit
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: September 17, 2002
Received: September 18, 2002

Dear Mr. Chappell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Applicant: McKinley Infuser, LLC

510(k) Number (if known): K023098

Device Name: Accufuser, Accufuser Plus, Standard Procedure Kit

Indications for Use:

The Accufuser and Accufuser Plus systems are intended for general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, intra-arterial and epidural, and into the intra-operative (soft tissue / body cavity) site. The Accufuser Plus is also intended for patient-controlled infusion using the integrated bolus button. General infusion uses include pain management for preoperative, perioperative and postoperative surgery.

The Accufuser and Accufuser Plus systems are also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

The Accufuser/Accufuser Plus system is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K023098

(Optional Format 3-10-98)